Remarks:

Applicant has read and considered the Office Action dated May 16, 2008 and the references cited therein. Claims 1 and 6 have been amended. Claims 1-6 are currently pending. Reconsideration and reexamination are hereby requested.

In the Action, claim 1 was rejected 35 U.S.C. § 112, second paragraph as being indefinite. The Office Action suggested amending the claim to positively recite active steps. Applicants thank the Examiner for the suggestions. Claim 1 has been amended as suggested in the Office Action. Applicant asserts that the rejection has been overcome. Moreover, Applicant notes that there appears to have been a typographical error in line 6 of claim 1. Claim 1 has been amended to correct this error. Applicant asserts that the rejection under 35 U.S.C. § 112, second paragraph should be withdrawn.

Claims 1-6 were rejected under 35 U.S.C. § 102(b) as being anticipated by Brandt et al. Applicant respectfully traverses the rejection.

Applicant notes that the Office Action indicates that Brandt et al. describes a method of "density gradient and immunomagnetical separation of blood-borne prostate e-derived cells and cell clusters from freshly obtained peripheral blood of patients." The Office Action cites page 4556 of Brandt et al. The Office Action states the cells obtained by this method were labeled with an anti-PSA antibody conjugated with FITC. Applicant asserts that this does not anticipate claim 1 and in particular, claim 1 as now amended. Claim 1 recites only the steps related to macrophages.

Upon careful reading of Brandt et al. it can be seen that the article is directed to two distinct methods of characterizing cells. In the first method described on page 4556, the steps are as follows:

A blood sample is taken of 100 μl of EDTA- treated unseparated peripheral blood cells with

single surface staining followed by treating with anti-PSA-FITC, anti-CD14-PE or anti-CD45-PE. The red blood cells are then sorted.

Applicants assert that this method found no relation between malignant and benign prosthetic conditions. Moreover, this result would have been known earlier.

Brandt et al. also teaches a method related to Buoyant Density Gradient on page 4556 in the right column. Again blood samples of 5ml of EDTA-treated blood are drawn and then sent to centrifuge. The single band of cells between the interface of the plasma is removed. The treatment removes the macrophages leaving epithelial cells. Following this intracellular staining is performed to arrive at cytokeratin.

The buoyant density gradient centrifuging is conducted with the density 1.068g/ml to enrich the epithelia cells, such as prostate cells. This is to the main subject of the Brandt article related to micrometastases and can not deal with macrophages as they are not present in the solution that is analyzed after the buoyant density gradient configuration used by Brandt. Therefore, the only method described in the article of Brandt that uses gradient centrifuging is not related to macrophages and is not suitable for characterizing and/or classifying macrophages as this type of cell is systematically excluded from the isolation procedure of Brandt using the buoyant density gradient of 1.068g/ml. Therefore, the same cells that are isolated with the prescribed buoyant density gradient centrifuging are labeled with an anti-PSA antibody conjugated with FITC as stated in the Office Action. However, it could be seen that these cells are not macrophages and do not include macrophages since the macrophages are eliminated in the previous step and are not available for characterizing and/or classifying steps, as recited in present claim 1.

Referring back to the first method described in the Brandt article, this method includes only a surface staining and not intercellular staining after appropriation of the cells since a perforation step is not part of that method described in the Brandt article. The first method is not comparable with the method recited in claim 1 since claim 1 requires intercellular staining being performed. Moreover, an analysis of macrophages is not performed in the Brandt article. It can be seen that on the Figures on page 4558, areas R1-R4 do not show macrophages, but only mononucleated cells, granulocytes, lymphocytes and monocytes. Therefore, it can be seen that an area for macrophages is not shown or suggested in the article or in Fig. 1. It can further be seen that the classification and circulating is related only to macrophages and not to all large mononuclear blood cells. It can be seen that Brandt is not related to this method as discussed above.

Moreover, Applicant asserts that the Brandt article describes methods that were conducted when it was believed that cancer could be detected at an early stage for blood borne cancer cells for measuring the malignancy isolated from the peripheral blood. Such a method is described in the article entitled, "Predictive Laboratory Diagnostics in Oncology Utilizing Blood-Borne Cancer Cells – Current Best Practice and Unmet Needs", also authored by Brandt and others. It can be seen that Brandt is directed to different types of blood-borne epithelial cells and in particular to cancer cells located in the blood and not to macrophages. These methods are further described in the other Brandt article entitled, "Two-Layer Buoyant Density Centrifugation Gradient for Enrichment of Prostate-Derived Cells and Cell Clusters from Peripheral Blood", published in Clinical Chemistry at the same time as the cited Brandt reference. This article again describes isolating prostate cancer cells and cell clusters, but not macrophages. Prostate-derived cells were identified with anti-cytokeratin antibodies and re-visualized in the same manner as described in the cited Brandt et al. article. Applicants also note that the article entitled, "Circulating Prostate-Specific Antigen/CD14-Double-Positive Cells: a Biomarker Indicating Low Risk for Hematogeneous Metastasis of Prostate Cancer", published in

the Journal of National Cancer Institute, further clarifies that Brandt et al. do not investigate macrophages and research was directed to circulating cancer cells.

In summary, it can be seen that the prior art clarifies that Brandt et al. article is not directed to performing the steps for macrophages. Moreover, Applicant asserts that all the presently recited steps are not shown or suggested by the Brandt et al. article or any other prior art or combination thereof. When properly construed and when reading the claim now directed only to macrophages, it can be seen that the prior art neither teaches nor suggests the method recited in claim 1. Applicant asserts that claim 1 patentably distinguishes over the prior art and requests that the rejection be withdrawn.

A speedy and favorable action in the form of a Notice of Allowance is hereby solicited. If the Examiner feels that a telephone interview may be helpful in this matter, please contact Applicant's representative at (612) 336-4728.

Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers or any future reply, if appropriate. Please charge any additional fees or credit overpayment to Deposit Account No. 13-2725.

Respectfully submitted,

MERCHANT & GOULD P.C.

Dated: 9/17/09

By: _____
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